NOV - 3 2006

510(K) SUMMARY

SONARA TCD SYSTEM (INCLUDING SONARA AND SONARA/TEK)

510(k) Number: K060421

Applicant's Name: VIASYS Healthcare, Inc.
227 Washington St., Suite 200
Conshohocken, PA 19428

Sponsor Contact: Mr. Glen Hermanson
Global Manager, Quality Engineering
VIASYS NeuroCare, Inc.
5225 Verona Road
Madison, WI 53711
Phone: 608 441-2065
Fax: 608 441-2007

Date Prepared: September 29, 2006

Trade Name: Sonara and Sonara/tek Transcranial Doppler (TCD) System

Classification Name: CFR Classification section 892.1550 (Product code IYN); CFR Classification section 892.1570 (Product code ITX)

Classification: Class II medical Device

Predicate Device: The Sonara and Sonar/tek TCD devices are comparable to the following predicate devices:

- Doppler-Box (K051085) manufactured by Compumedics Gmbh (DWL). Doppler-Box is a Transcranial Doppler Ultrasound device, providing similar data to the Sonara/tek device.
- TCD 100M (K002533) manufactured by Spencer Technologies. TCD 100M is a Transcranial Doppler Ultrasound device, providing similar data to the Sonara device.
- TC8080 Pioneer /Companion III (K053648) manufactured by VIASYS HealthCare, Inc., Neurocare Group. The TC8080 Pioneer / Companion III are TCD devices with equivalent indications for use.

Device Description: The Sonara device is a Transcranial and peripheral vascular Doppler system, which is designed to measure blood flow velocities and other hemodynamic parameters in a non-invasive manner, in intracranial, extracranial and peripheral blood vessels.
The Sonara system includes an integrated 15" touch screen color LCD display, integrated PC board and hard disk for data management and

display. The Sonara/tek is the same device, utilizing a personal computer for its operation (via USB connection). The TCD system supports 2MHz, 4MHz and 8MHz ultrasound probe frequencies, either in a unilateral or bilateral configuration. For monitoring purpose, a special 2MHz monitoring probe (which fits into a headset) is provided. Online and Offline modes of operation are available. The system also includes a remote control and footswitch as accessories.

Intended Use / Indication for Use: The Sonara and Sonara/tek Transcranial Doppler are medical ultrasound devices for measuring the blood flow velocities in arteries and in veins noninvasively, consistent with the FDA Ultrasound System and Transducer Indication for Use forms cleared with the 510(k).

Performance Standards: None.

The design of the Sonara and Sonara/tek Transcranial Doppler (TCD) devices conforms to the following voluntary standards:
IEC/EN-60601-1: Medical Electrical Equipment; Part 1: General Requirements for Safety. Second edition (1990), including amendments #1(1993), #2(1995), #13(1996).
IEC/EN 60601-1-2: Medical Electrical Equipment; Part 1-2: Collateral Standard: Electromagnetic Compatibility- Requirements and Tests (2001)
IEC/EN 60601-2-37: Medical Electrical Equipment; Part 2: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment (2001)

Acoustic Output: Acoustic output reporting for the Sonara devices was carried in compliance with "Information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers", September 30, 1997 (FDA Ultrasound Guidance (1997), Table 6-3, Page 6-9.

Test Data: The Sonara and Sonara/tek Transcranial and vascular Doppler devices have been subjected to extensive safety, performance testing, and validation before release. Final testing of the Sonara device included various performance tests designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

Substantial Equivalence: The Sonara and Sonara/tek TCD are similar to currently distributed pulsed Doppler Ultrasound systems with 2MHz, 4MHz and 8MHz transducers intended for transcranial and peripheral Doppler applications. Maximum acoustic output levels are below pre-amendment levels for acoustic intensity for this application, and for Mechanical Index for all applications. Power levels are displayed at all times during scanning. A standard spectrum display is shown in both viewing

formats. The device includes an M-mode image. All of the above features are similar to these features in the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to Predicate devices is that the Sonara and Sonara/tek Transcranial and peripheral vascular Doppler device and transducers are substantially equivalent in safety and efficacy to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

VIASYS Healthcare, Inc., NeuroCare Group
% Mr. Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
MADISON WI 53711

Re: K060421
Trade Name: Sonara and Sonara/tek Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN and ITX
Dated: October 6, 2006
Received: October 10, 2006

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonara and Sonara/tek Systems, as described in your premarket notification:

Transducer Model Number

2 MHz PW Hand-Held Transducer
2 MHz PW Monitoring Transducer
4 MHz Transducer
8 MHz Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Dr. Ewa Czerska at (240) 276-3666 .

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Sonara System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic				X						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The Sonara device can be used during surgery to support Transcranial Doppler Monitoring, Carotid Monitoring, Emboli Detection (HITS).

No associated transducer probes are applied invasively.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060421

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic				X						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The Sonara/tek device can be used during surgery to support Transcranial Doppler Monitoring, Carotid Monitoring, Emboli Detection (HITS).

No associated transducer probes are applied invasively.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060421

2 MHz PW Hand-Held Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic				X						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Intraoperative: Noninvasive use during surgery to support Transcranial Doppler Monitoring, Carotid Monitoring, Emboli Detection (HITS).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

F-510(k) Number K060421

2 MHz PW Monitoring Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic				X						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Intraoperative: Noninvasive use during surgery to support Transcranial Doppler Monitoring, Carotid Monitoring, Emboli Detection (HITS).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060421

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Intraoperative: Use during surgical procedures to support noninvasive extracranial monitoring.

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Prescription Use (Per 21 CFR 801.109)

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510(k) Number K060421

8 MHz Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				X						
Intraoperative Neurological										
Pediatric				X						
Small Organ (specify)										
Neonatal Cephalic				X						
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Intraoperative: Use during surgical procedures to support noninvasive extracranial monitoring.

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